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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,534	06/01/2006	Christopher John Burns	415852000200	6170

25225 7590 12/20/2010  
MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER
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WILLIS, DOUGLAS M

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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12/20/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,534	<b>Applicant(s)</b> BURNS ET AL.	
	<b>Examiner</b> DOUGLAS M. WILLIS	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12, 14, 21-23, 26, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 24 and 27 is/are rejected.
- 7) ☒ Claim(s) 25 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

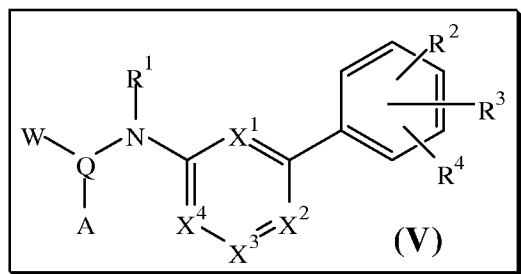
## DETAILED ACTION

### Status of the Claims / Priority

Claims 10-12 and 14-30 are pending in the current application. According to the Claim Amendments, filed December 6, 2010, claims 10, 11, 15, 18, 20 and 23-26 were amended and claims 1-9 and 13 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2004/001689, filed December 3, 2004, which claims priority under 35 U.S.C. § 119(a-d) to AU 2003906680, filed December 3, 2003.

### Status of Restrictions / Election of Species

Applicant's affirmation of the following election, without traverse, in the reply filed on



April 15, 2010, is acknowledged: a) Group II - claims 10-12, 14 and 21-30, where  $X_1 = -N-$ ;  $X_2 = -N-$ ;  $X_3 = -C-$ ; and  $X_4 = -C-$ ; and b) substituted pyrimidine of formula (V) - p. 48, example 18.

The requirement was made FINAL in the Non-Final Rejection, mailed on February 2, 2010.

This application contains claims 15-20, drawn to nonelected inventions, without traverse, in the reply filed on December 6, 2010. A complete reply to the final rejection may include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.02.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action,

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may be found in either the Non-Final Rejection, mailed on February 2, 2010, the Final Rejection, mailed on May 25, 2010, or the Non-Final Rejection, mailed on October 12, 2010. Furthermore, any rejections and/or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the Claim Amendments, filed December 6, 2010.

Thus, a third Office action and prosecution on the merits of claims 10-12, 14 and 21-30 is contained within.

### **New Claim Objections**

Claim 25 is objected to because of the following informalities: the claim is dependent upon a rejected base claim. Appropriate correction is required.

Claim 28 is objected to because of the following informalities: the claim is dependent upon an objected base claim. Appropriate correction is required.

### **New Claim Rejections - 35 U.S.C. § 103**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

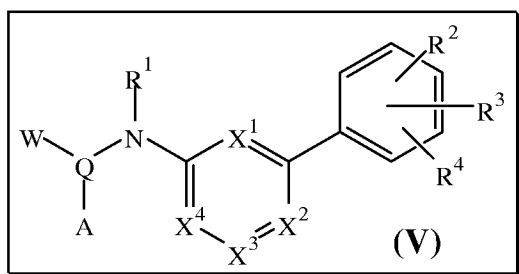
1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding, et al. in WO 03/031406.

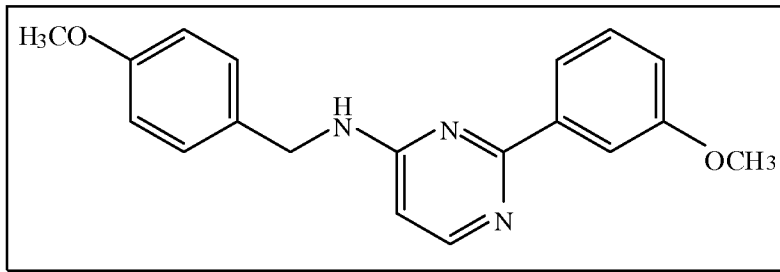
The instant application recites substituted pyrimidines and compositions of the formula



(V), shown to the left, where  $X^1 = -N-$ ;  $X^2 = -N-$ ;  $X^3 = -CY-$ , wherein  $Y = -H$ ;  $X^4 = -CY-$ , wherein  $Y = -H$ ;  $Q = -CH-$ ; **W** = **-C<sub>1-4</sub>alkyl**; **A** = -aryl, substituted with p-OC<sub>1-4</sub>alkyl;  $R^1 = -H$ ;  **$R^2 = -m-C_{1-6}$ alkylhetaryl**;  $R^3 = -$

H; and  $R^4 = -H$ , as tubulin inhibitors.

Ding, et al. (WO 03/031406), as provided in the file and cited in the IDS, teaches substituted pyrimidines and compositions, shown to the right, where  $X^1 = -N-$ ;  $X^2 = -N-$ ;  $X^3 = -CY-$ , wherein  $Y = -H$ ;  $X^4 = -CY-$ ,



wherein  $Y = -H$ ;  $Q = -CH-$ ; **W** = **-H**; **A** = -phenyl, substituted with p-OCH<sub>3</sub>;  $R^1 = -H$ ;  **$R^2 = -m-OCH_3$** ;  $R^3 = -H$ ; and  $R^4 = -H$ , as kinase inhibitor scaffolds {p. 42, Table 2, entry 1; and compositions - p. 34, ¶[0132]}. Moreover, in the genus disclosure, Yonetoku teaches that  $R^2$  may alternatively be -C<sub>1-6</sub>alkylhetaryl [R<sub>4</sub>-R<sub>8</sub>: heteroarylalkyl - p. 12, lines 1-7].

The differences between the instantly recited substituted pyrimidines and compositions of the formula (V) and Ding's substituted pyrimidines and compositions are: a)  $R^2$  is -C<sub>1-6</sub>alkylhetaryl in the instantly recited substituted pyrimidines and compositions of the formula (V), whereas  $R^2$  is -OCH<sub>3</sub> in Ding's substituted pyrimidines and compositions; and b) **W** is -CH<sub>3</sub>

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in the instantly recited substituted pyrimidines and compositions of the formula (V), whereas W is -H in Ding's substituted pyrimidines and compositions.

In the chemical arts, it is widely accepted that structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness. {See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting *In re Dillon*, 919 F.2d 688, 692 [16 USPQ2d 1897] (Fed. Cir. 1990) (en banc)); and *In re Papesch*, 315 F.2d 381 [137 USPQ 43] (C.C.P.A. 1963)}.

Similarly, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. {See *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA 1954); and *Ex parte Henkel*, 130 USPQ 474 (POBA 1960)}.

Consequently, since: a) Ding teaches substituted pyrimidines and compositions, where R<sup>2</sup> is -OCH<sub>3</sub>; b) Ding teaches substituted pyrimidines and compositions, where -OCH<sub>3</sub> and -C<sub>1-6</sub>alkylhetaryl are alternatively usable at R<sup>2</sup>; c) Ding teaches substituted pyrimidines and compositions, where W is -H; d) the courts have recognized that structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a

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prima facie case of obviousness; and e) the courts have further recognized that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results, one having ordinary skill in the art, at the time this invention was made, would have been motivated to utilize the teachings of Ding and (1) replace the  $-OCH_3$  at  $R^2$  in Ding's substituted pyrimidines and compositions, with an alternatively usable  $-C_{1-6}$ alkylhetaryl, and (2) replace the  $-H$  at  $W$  in Ding's substituted pyrimidines and compositions, with an alternatively usable  $-CH_3$ , with a reasonable expectation of success and similar therapeutic activity, rendering claims 24 and 27 obvious.

Finally, although not explicitly discussed herein, applicant is advised to note that the Ding reference contains additional species that may obviate the instantly recited substituted pyrimidines of the formula (V). Consequently, any amendments to the claims and/or arguments formulated to overcome rejections rendered under 35 U.S.C. § 103(a) should address this reference as a whole and should not be limited to the species discussed or disclosed explicitly herein.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

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### **Allowable Subject Matter**

Claims 10-12, 14, 21-23, 26, 29 and 30 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The limitation on the core of the substituted pyrimidines and tubulin inhibitors of the formula (V) that is not taught or fairly suggested in the prior art is R<sup>2</sup> on the periphery of the pyrimidine core. This limitation is present in all of the recited species in claims 11, 12 and 29, respectively.

Consequently, the species recited in claims 11, 12 and 29, respectively, are neither anticipated, nor reasonably obviated, by the prior art.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### **Conclusion**

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,



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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, AU 1624**